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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,664	05/02/2005	Andrzej Czernecki	POL0005-PCT	5014

36183 7590 03/09/2007  
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EXAMINER
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TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/506,664

Applicant(s)

CZERNECKI ET AL.

Examiner

Rene Towa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3,4 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4 and 8-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This Office is responsive to an amendment filed December 11, 2006. Claims 3-4 & 8-19 are pending. Claims 8-19 are amended. No new claim has been added. Claims 1-2 and 5-7 are cancelled.

***Claim Objections***

2. The objections are withdrawn due to amendments.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 12 & 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutynowski et al. (US Patent No. 6,613,064) in view of Simons et al. (US Patent No. 5,871,494).

In regards to claim 12, Rutynowski et al. disclose a puncturing device for regulating force of puncture comprising:

a sleeve 1 having a first end and second end, and defining a sleeve axis;

a push element 2 located at the first end of the sleeve 1;

a piston 5 slidably mounted within the sleeve 1, the piston 5 having a wing 12 configured to rest on an edge of the sleeve 1 and prevent the piston 5 from sliding through the sleeve 1, and the piston 5 having a puncturing tip 8 on a side of the piston 5 opposite to the first end of the sleeve 1; and

a drive spring 10 within the sleeve 1 and compressed between the push element 2 and the piston 5, and

the drive spring 10 being compressed until the push element 2 presses the piston 5 sufficiently enough to break the wing 12, at which point the drive spring 10 expands and drives the piston 5 toward the second end of the sleeve 1 (see figs. 1-2 & 4; column 2/lines 1-7 & 11-22; see claim 3 of Rutynowski et al.).

In regards to claim 17, Rutynowski et al. disclose a device wherein the wing 12 configured to rest on an upper edge 13 of the sleeve 1 (see fig. 4).

In regards to claim 18, Rutynowski et al. disclose a device wherein the piston 5 having a second wing 12 configured to rest on an edge 13 of the sleeve 1 (see fig. 4).

In regards to claim 19, Rutynowski et al. disclose a device wherein the piston comprising a central body 5, a push rod 6 on a side of the central body proximate to the first end of the sleeve 1, and a fin 7 on a side of the central body proximate the second end of the sleeve 1, wherein the push element 2 presses on the push rod (see figs. 1-2 & 4).

Rutynowski et al. disclose a device, as described above, that teaches all the limitations of the claims except Rutynowski et al. do not disclose a force-adjusting member.

However, Simons et al. disclose a device 500 comprising a force-adjusting member (502, 528) turnably mounted on the device body 526; wherein the force

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adjusting member (502, 528) adjusts a distance within which the spring 532 is compressed (see figs. 5A-B & 6A-F; column 4/lines 8-20; column 11/lines 39-52; column 12/lines 55-64).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. with a force-adjusting member similar to that of Simons et al. in order to customize the lancing force to provide an adequate blood sample and to minimize pain (see Simons et al., column 4/lines 8-11).

5. Claims 3-4, 8-11 & 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutynowski et al. ('064) in view of Simons et al. ('494) further in view of Chelak et al. (US Patent No. 6,558,402).

Rutynowski et al. as modified by Simons et al. discloses a device, as described above, that teaches all the limitations of the claim except Rutynowski et al. as modified by Simons et al. do not teach a force-adjusting member comprising an inwardly directed pair of oblique half-ring, or stair-shaped or gradient shaped member.

However, Chelak et al. disclose a device comprising a stair-shaped or gradient shaped member 106 (see fig. 3D).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of except Rutynowski et al. as modified by Simons et al. with a half ring, stair-shaped or gradient member similar to that of Chelak et al. since such a modification would amount to a design choice that serves the same purpose of varying the pre-load (i.e. perhaps by

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modifying the trigger system of Simons et al. to include a stair or gradient shaped member instead). Moreover, it has previously been held that merely changing the shape (i.e. shape of the trigger) is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. as modified by Simons et al. and Chelak et al., above, with a force-adjusting member mounted at a proximal end thereof since such a modification would amount to a design choice. It has previously been held that merely shifting location of parts is not patentable--See *In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).

### ***Response to Arguments***

6. Applicant's arguments filed December 11, 2006 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

A handwritten signature in black ink, appearing to read "M. H. Lindsey", is located in the lower right quadrant of the page.